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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Angelica Malmberg

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EXAMINER

HAWTHORNE, OPHELIA ALTHEA

ART UNIT

PAPER NUMBER

4148

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,770	<b>Applicant(s)</b> MALMBERG ET AL.	
	<b>Examiner</b> OPHELIA HAWTHORNE	<b>Art Unit</b> 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>30 March 2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1 – 6, 8, 11, 13, 20 - 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller (US 6,032,670)** in view of **Marshall (US 4,873,997)**.

**Regarding claim 1**, Miller discloses a fluid collection pouch (**figure 1**), (23;23';27) made of flexible plastic material (**[Col. 4], line 39**) for surgical drapes or towels (24,25), which consists of two layers (**[Abstract], lines 8 - 10**) and comprises an opening along which said layers are unattached to each other (**[Abstract], lines 10**), and two side edges (10A, 10B, IIA, IIB; 10A',I0B';31,33 AND 30,32) extending on opposite sides of the opening along which said layers are attached to each other, characterized in that at least one portion (12,13,10,11;12',13',10'; 30,32).

Miller fails to disclose at least one of the layers of the pouch comprises at least one bellows-fold.

However, Marshall teaches a central sheet comprising of a pair of pleats **(22)** and **(24)**, **figure 3**.

Given the teachings of Marshall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder procedures of Miller with at least one of the layers of the pouch comprising at least one bellows-fold. Doing so would serve as an effective barrier to fluid run-off and provides an efficient means for channeling fluids into the fluid collection pouch.

**Regarding claim 2**, Miller fails to disclose the pouch is characterized in that each of the side edge parts of the pouch (12, 13; 12', 13'; 30, 32) comprises at least one portion containing a bellows-fold.

However, Marshall teaches a central sheet comprising of a pair of pleats **(22)** and **(24)**, **figure 3**.

Given the teachings of Marshall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder procedures of Miller with at least one of the layers of the pouch comprising at least one bellows-fold. Doing so would serve as an effective barrier to fluid run-off and also provide an efficient mean for channeling fluids into the fluid collection pouch.

**Regarding claim 3**, Miller discloses the pouch is characterized in that one (9; 9') of the two layers (9, 10, 11; 9', 10') constituting the pouch extends beyond the edge of the second layer **(figure 1)**.

Miller fails to disclose the pouch has bellows-folded side edges (12, 13; 12', 13').

However, Marshall teaches a central sheet comprising of a pair of pleats **(22)** and **(24)**, **figure 3**.

Given the teachings of Marshall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder procedures of Miller with at least one of the layers of the pouch comprising at least one bellows-fold. Doing so would serve as an effective barrier to fluid run-off and provides an efficient means for channeling fluids into the fluid collection pouch.

**Regarding claim 4**, Miller discloses that the pouch is manufactured of one piece of material **([Col. 5], lines 5 – 7)**.

**Regarding claim 5**, Miller discloses the pouch characterized in that the pouch (23) is manufactured of a rectangular piece of material **([Col. 4], lines 32 – 33)**, whereby one of the layers of the pouch is constituted by two similarly shaped end parts having the form of right-angled triangles **([Col. 4], lines 41 – 42)**, **figure 1** which are folded in against each other and affixed to each other in a flange-like seam (4,5) and which together with the end-part of the piece of material over which said two similarly shaped end-parts have been folded, constitute the collection part (10, 11) of the pouch having the shape of a cone **(figure 1)**.

**Regarding claim 6**, Miller discloses the pouch is characterized in that drainage pipes or tubes are affixed to the bottom of the cone-shaped collection part **([Col. 4], lines 47 – 50)**.

**Regarding claim 8**, Miller discloses a method of manufacturing a fluid collection pouch (**figure 1**), made of flexible plastic material (**[Col. 4], line 39**) for surgical drapes or towels, consisting of two layers (**[Abstract], lines 8 - 10**) and comprising an opening along which said layer are unattached to each other (**[Abstract], lines 10**), and two side edges extending on opposite sides of the opening along which said layers are attached to each other, characterized by the following steps; providing a pouch blank comprising two identical (**[Col. 4], lines 24 – 25**) rectangular layers (**[Col. 4], line 31**) of flexible plastic material (**[Col. 4], line 30**) having two opposing long sides (**58**), **figure 4A**) and two opposing short sides (**50**), **figure 4A**), said layers being placed on top of each other so that their long and short sides lie edge-to-edge and having the edge parts along one long side and at least one short side joined to each other, thereafter folding out the long sides from each other until they are located in the same plane, whereby the end or ends (10,11) of the material piece having the edges of the short sides joined to each other assume a cone-shape by being folded about folding lines inclined to the length direction and by the short side edges joined to each other being folded in against the material piece and extending along the length symmetry axis (A-A) of the pouch (**[Col. 4], lines 33 – 45**).

Miller fails to disclose bellows-folding the longitudinal edge parts of the pouch blank either before or after said folding out of the long sides so that the bellows-folds (12,13) are located on the same side of the pouch blank (I) as the edges of the short sides that have been folded in, whereby a fluid collection pouch is formed.

However, Marshall teaches pleats that are capable of being incorporated along the longitudinal edge parts of the pouch blank either before or after said folding out of the long sides (**[Col. 5], lines 5 – 7**).

Given the teachings of Marshall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder procedures of Miller comprising of bellows-folding the longitudinal edge parts of the pouch blank either before or after said folding out of the long sides so that the bellows-folds (12,13) are located on the same side of the pouch blank (1) as the edges of the short sides that have been folded in, whereby a fluid collection pouch is formed. Doing so would serve as an effective barrier to fluid run-off and provides an efficient means for channeling fluids into the fluid collection pouch.

**Regarding claim 11**, Miller discloses placing a coupling (6,7) to drainage pipes or tubes between the edge parts of the shorts sides (4,5) being folded in against each other (**[Col. 4], lines 47 – 50**).

**Regarding claim 13**, Miller discloses the pouch is characterized in that one (9; 9') of the two layers (9, 10, 11; 9', 10') constituting the pouch extends beyond the edge of the second layer (**figure 1**).

Miller fails to disclose the pouch has bellows-folded side edges (12, 13; 12', 13').

However, Marshall teaches a central sheet comprising of a pair of pleats (**22**) and (**24**), **figure 3**.

Given the teachings of Marshall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder

procedures of Miller with at least one of the layers of the pouch comprising at least one bellows-fold. Doing so would form barriers against bodily fluids and act as a fluid flow mechanism.

**Regarding claim 20**, Miller discloses placing a coupling (6,7) to drainage pipes or tubes between the edge parts of the shorts sides (4,5) being folded in against each other ([Col. 4], lines 47 – 50).

**Regarding claim 21**, Miller discloses placing a coupling (6,7) to drainage pipes or tubes between the edge parts of the shorts sides (4,5) being folded in against each other ([Col. 4], lines 47 – 50).

4. **Claims 7 & 14 – 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller (US 6,032,670)** in view of **Marshall (US 4,873,997)** and further in view of **Jones (US 4,905,710)**.

**Regarding claims 14 – 18**, Miller invention, as modified by Marshall, fails to disclose wherein the folded parts in the bellows-folds (12,13) are joined to each other in one or several portions (14,15,16) along the length of the bellows-folds.

However, Jones teaches wherein the folded parts in the bellows-folds (12,13) are joined to each other in one or several portions (14,15,16) along the length of the bellows-folds **(13), figure 1**.

Given the teachings of Jones, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder procedures of Miller modified by Marshall wherein the folded parts in the bellows-folds (12,13) are joined to each other in one or several portions (14,15,16) along the length of



the bellows-folds. Doing so would serve as a means for holding the bellow folds in their contracted form and prevents unfolding of the bellow folds.

5. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Miller (US 6,032,670)** in view of **Marshall (US 4,873,997)** and further in view of **Ewonce et al. (US 6,725,864 B2)**.

**Regarding claim 9**, Miller invention, as modified by Marshall, discloses the method, characterized by providing the pouch blank by folding a piece of flexible plastic material **([Col. 4], line 39)** having a rectangular shape **([Col. 4], line 31)** comprising two opposite long sides (2,3) **(58), figure 4A)** and two opposite short sides **(50), figure 4A)**, about a central longitudinal folding line (A-A) so that the long and short sides are located edge-to-edge to each other.

Miller fails to disclose whereafter the two end parts folded against each other of at least one of the short sides are joined to each other.

However, Ewonce et al. teaches a surgical shoulder drape with pouch comprising of the two end parts folded against each other of at least one of the short sides are joined to each other **([Col. 3], lines 52 – 55), (15), figure 2)**.

Given the teachings of Ewonce et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a surgical drape for shoulder procedures of Miller, modified by Marshall, comprising of two end parts folded against each other of at least one of the short sides are joined to each other. Doing so would serve as a tight-seal for the collecting pouch.

**Regarding claim 10 and 19**, it would have been obvious to one of ordinary skill in the art at the time the invention was made to fold the transverse edge part of the cone-shaped part or the transverse edge parts (17,18) of the cone-shaped parts (10, 11) of the formed collection pouch in over or under the edge part in question after the bellows-folding of the longitudinal edge parts of the material piece. Doing so would form an integral trough that will further channel fluids into the fluid collection pouch.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is (571) 270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4148

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ophelia Hawthorne/  
Examiner, Art Unit 4148

**/Terrell L Mckinnon/**

**Supervisory Patent Examiner, Art Unit 4148**